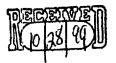


67658

October 25, 1999

Express Mail Label No.



Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. S.W. Washington, D.C. 20204

RE: Notification of marketing a dietary supplement that bears on its label or its labeling a statement provided for in section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

Dear FDA Consumer Safety Officer:

USANA, Inc. submits this notification for its dietary supplement products that bear statements of nutritional support in accordance with section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

**Manufacturer of Dietary Supplement:** 

USANA, Inc.

3838 West Parkway Blvd.

Salt Lake City, Utah 84120-6336

Name of Dietary Supplements:

(including brand name) "Mega

Antioxidant, Chelated Mineral, "Body Rox", "Usanimals", "Coquinone", "Garlic EC",

"OptOmega", "E-Prime", "Poly C",

"Palmetto Plus", "PhytoEstrin", "Melatonin

KL", "Gingko PS", "St. John's Wort",

"LEAN Team Formula".

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#### Text of Statements Being Made for "Mega Antioxidant":

"A comprehensive, high-potency formula that delivers the full spectrum of vitamins, antioxidants, and cofactors needed for long-term optimal health."

"Provides advanced, balanced amounts of the essential vitamins and cofactors to support a robust and vigorous metabolism."

LET 456/

"Contains 15 antioxidant ingredients to give comprehensive, "full body" protection from oxidative stress."

"Vitamin A promotes healthy skin and immune system, and is important for good vision."

## Text of Statements Being Made for "Chelated Mineral":

Selenium is an essential component of the glutathione peroxidase antioxidant system and also plays an important role in thyroid hormone metabolism.

We now know that boron plays a critical role in the metabolism of calcium and magnesium in healthy bone growth.

## Text of Statements Being Made for "Body Rox":

An important – and sometimes primary – function of certain vitamins and minerals, such as vitamin E and Selenium, is to protect cells from free-radical damage.

Body Rox provides a potent combination of antioxidants to assist young bodies in achieving ideal health.

Vitamin A, derived from beta-carotene, is important for vision and healthy skin.

Selenium, one of the major minerals in Body Rox, has been proven to aid in body growth and development, which is critical during the teenage years.

### Text of Statements Being Made for "Usanimals":

Vitamins E and C, two of the most powerful antioxidants needed by the human body.

Vitamin E is one of the most important antioxidants because it helps to maintain strong cell membranes.

In addition to its antioxidant role, vitamin C is essential for the manufacture of collagen, the main protein substance in the body.

### Text of Statements Being Made for "Coquinone":

Promotes a strong and healthy cardiovascular system

Provides a potent antioxidant.

Supports robust energy metabolism in muscles to optimize athletic performance.

# Text of Statements Being Made for "Garlic EC":

Broad spectrum of benefits including healthy cardiovascular, immune, and respiratory functions.

### Text of Statements Being Made for "OptOmega":

Broad spectrum of benefits including cardiovascular health, improved immune function, mental acuity, and healthy skin.

The prostaglandins are important hormone-like substances that mediate several important functions, including inflammation, blood pressure, platelet aggregation, immune and allergic response, relaxation of blood vessels, and improving circulation.

## Text of Statements Being Made for "E-Prime":

Numerous clinical trials and epidemiological data show that vitamin E levels many times higher than the RDA on average (400 to 800 IU per day) can provide significant health benefits.

### Text of Statements Being Made for "Poly C":

Acts as a free radical scavenger.

Strengthens the immune system, is important in the synthesis of collagen, and promotes cardiovascular health.

#### Text of Statements Being Made for "PhytoEstrin":

Addresses a number of health issues affecting women relating to hormone changes and hormone release patterns.

#### Text of Statements Being Made for "Palmetto Plus":

Recently 18 randomized clinical studies revealed that about 80 to 90 percent of men using saw palmetto showed a positive correlation between saw palmetto and prostate health.

USANA uses saw palmetto for its prostate formula because considerable clinical research has shown the herb to be a powerful aid for promoting and maintaining prostate health.

# Text of Statements Being Made for "Melatonin KL":

Provides your body a natural way to adjust sleep patterns.

# Text of Statements Being Made for "Gingko-PS":

Gingko biloba is a vasodilator that improves blood circulation in the brain.

PS is clinically proven to enhance memory.

# Text of Statements Being Made for "St. John's Wort":

Promotes a healthy mental attitude and a positive outlook on life.

#### Text of Statements Being Made for "LEAN Team Formula":

Promotes Lipolysis and thermogenesis

Increases physical performance and helps build lean muscle mass.

#### John B. McCandless declares:

- 1. That he is Senior Vice President and Chief Operating Officer of Usana, Inc. (hereinafter "applicant") and is authorized to make this declaration;
- 2. That information contained in this statement is complete and accurate, and that USANA, Inc. has substantiation that the statement is truthful and not misleading.

DATED this 26 day of October, 1999.

USANA, INC.

By:

John B. McCandless

Senior Vice President and Chief Operating Officer